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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/916,465	07/26/2001	Gordon A. Andrews	55280	8758

27148 7590 12/29/2003

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EXAMINER	
CHEU, CHANGHWA J	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 12/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/916,465	ANDREWS ET AL.	
	Examiner	Art Unit	
	Jacob Cheu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18,22 and 23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-3,6-18,22 and 23* is/are allowed.

6)☒ Claim(s) *4-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's amendment filed on 11/03/2003 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claim 11 is amended.
2. Declaration under 37 CFR §1.131 is submitted.

Deposit

1. Claims 4 and 5 are rejected under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention and failing to provide an enabling disclosure, because the specification does not provide evidence that the claimed biological materials are (1) known and readily available to the public; (2) reproducible from a written description (e.g. sequenced); or (3) deposited.

Claims 4 and 5 are drawn to monoclonal antibodies, namely 13G3 and 4E10 for determining feline blood type. It is unclear if cell lines which produce antibodies having the exact chemical identity and properties of the antibodies designated 13G3 and 4E10 are known and publicly *available*, or can be reproducibly isolated without undue experimentation. Accordingly, filing of evidence of the reproducible production of the cell lines and antibodies necessary to practice the instant invention or filing of evidence of deposit is required. Without a publicly available deposit of the above cell lines, one of skill in the art could not be assured of the ability to practice the invention as claimed. *Exact replication* of: the claimed cell line; the cell lines which produce the chemically and functionally distinct antibodies claimed; and/or, the claimed antibody's amino acid or nucleic acid sequence is an unpredictable event.

Without a publicly available deposit of the above cell line, one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed. Exact replication of: (1) the claimed cell line; (2) a cell line which produces the chemically and functionally distinct antibody claimed; and/or (3) the claimed antibody's amino acid or nucleic acid sequence is an

unpredictable event. Deposit of the hybridoma would satisfy the enablement requirements of 35 U.S.C. § 112, first paragraph. See, 37 C.F.R. 1.801-1.809.

Response to Applicant's Arguments

The gist of applicant's arguments is based on (1) the 37 CFR §1.131 declaration submitted by the inventor indicating that the technology manufacturing of monoclonal antibodies recited in claims 4 and 5, namely 13G3 and 4E10 involves only routine skill in the art (See Declaration); and (2) *In re Wands* decision that such techniques of generating monoclonal antibodies will not impose undue experimentation to one artisan in the art. The applicant's arguments have been considered but appear not convincing.

First, the examiner would like to draw applicant's attention to the core of the issue- 13G3 and 4E10 monoclonal antibodies. The examiner does not question the feasibility of the *ordinary* monoclonal antibody technique. In fact, the instant claim 1 reciting the use of two monoclonal antibodies is an allowable subject matter. (See Office Action sent on 8/4/2003) This is consistent with the decision of *In re Wands* where court concluded that it would not require undue experimentation to obtain *antibodies* needed to practice the claimed invention. (See In re Wands, 8 USPQ2d 1407, last paragraph) Please note that there is *no particular monoclonal antibodies* been recited in *In re Wands*. *In re Wands* case merely recites *a monoclonal antibody* for an assay. (See *In re Wands*, page 1402)

Second, the main issue is on the enablement of the recited 13G3 and 4E10 monoclonal antibodies. The examiner would like to direct applicant's attention to the Table 1 of the instant specification. (page 14) This table is the designation of the monoclonal antibodies manufactured by the applicant using conventional hybridoma technology. What makes 13G3 and 4E10 monoclonal antibodies distinct is the characteristics of the agglutination test recorded in Table 1 with respect to feline Type A, B and AB. (page 14) With respect to each individual ratio, e.g. 13 G3 monoclonal antibody: 654/654, (type A), 0/31 (type B), 7/10 (type AB) and total number of samples tested (695), it would be undue experimentation to one skilled in the art to *duplicate the*

exact features as listed in Table 1 so as to qualify the antibodies as the designated 13G3 and 4E10 monoclonal antibodies. Therefore, it is the policy of the this Office that the recited 13G3 and 4E10 monoclonal antibodies must comply with the deposit rule for public access before granting a monopoly right to the inventor(s).

Allowable Subject Matter

1. Claims 1-3, 6-18, 22-23 are allowed.

The following is an examiner's statement of reasons for allowance: no prior art teaches or suggests determining feline blood type by using two distinct monoclonal antibodies at the same time where each monoclonal antibody recognizes at least one group feline blood specific A antigen. The same techniques were published by the inventors less than a year ago and had been sworn behind. (See Green et al. Comparative Haematology International (2000) 10: 30-37)

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 703-306-4086. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone number for the organization where this application or proceeding is assigned is 703-746-9434.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-3399.

Jacob Cheu
Examiner
Art Unit 1641

December 16, 2003

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
12/22/03